## ARGUMENTS FOR PATENTABILITY

It is requested that the Examiner reconsider her rejection of the claims in this application, as set forth in the Official Communication of December 15, 2009. Claims 6-8 correspond to the granted claims 1-3 of the European Patent. Claim 9 is directed to a structural feature described in the specification (see paragraphs [0031] - [0033]).

With respect to the rejection of the claims of 35 U.S.C. §1.112, claim 6 corresponds to claim 1 of the granted European patent and has been amended to eliminate the terms "considerable" and "considerably". Instead, the preamble sets forth that the nail is specially designed to work in long bones having a medullary cavity of a given length. The length of the thin rods is then defined as being less than the given length of the medullary cavity. Thus, claim 6 is properly definite.

The claims of Attachment C-1 are believed allowable for the following reasons.

Applicant's invention provides a nail which is operable to fixate two separate sections of a fractured long bone to facilitate knitting by maintaining tension tending to join the two sections. A detailed discussion was previously provided in Attachment B-3 filed September 15, 2009.

The Aginsky Patent No. US 4,227,518 relates to a supporting device for a comminutely fractured tubular bone, instrumental in keeping the bone fragments aligned by its insert into a the medullary cavity of the bone, until the bone structure has healed to its original size and strength.

The device comprises an outer tubular sheath 10, its leading or front end being shaped to form at least two expandable branches 11 which are adapted to be spread and pressed against the bone cavity walls by expandor body 12 and links 13 expanding. The front portion of the sheath, including the branches, is provided with circumferential serrations in saw shape, each serration decreasing in diameter from its front to its rear. The retraction nail further comprises a longitudinal bar 14 movable inside the tubular sheath and adapted actuate the said expanding means 12 and 13 by being manually operated from the trailing or rear end of the nail which latter protrudes by a short length out of the previously perforated bone end. An annular retraction body axially movable on the sheath end consist of a centrally perforated disc 15 and an internally threaded nut 16, the disc and the nut being interconnected in a manner permitting their relative rotation about their common axes, but not their relative axial movement.

The Summerlin Patent No. US 3,512,448 provides a blind fastener adapted to be anchored in a hole in a body, which fastener comprises a longitudinally tension-supporting member 12, an enlarged head member 13 at the head end of the fastener, a sleeve-like member 11 surrounding the tension-supporting member which sleeve-like member has an expansible part 15 at its tail end and a longitudinally collapsible part 19, and expansion means connected to the tension-supporting member at the tail end of the fastener operable to expand the expansible part of the sleeve-like member upon application of tension to the tension supporting member.

When the fastener is inserted into the hole with the head member abutting directly or indirectly against the body surface, and tension is applied to the tension-supporting member between the expansion means and the head member, the expansion means expands the expansible part of the sleeve-like member to grip the wall of the hole. Further tension causes the collapsible part 19 to contract lengthwise. It should be noted that in Column 5, lines 24-26 the inventor states that the struts deform circumferentially rather than radially outward, allowing the nut to be displaced to firmly press the sheet 37 tightly against the wall surface 34.

The combination of both documents do not destroys the inventive step, since the Summerlin US Patent No. 3,512,448 when applied to the wall anchor in its middle section remains rigid and only the body that is on the outside is the one that expands of the bottom, however in the present application, the tubular nail further includes a head (1) at its proximal end, from which the plurality of thin rods (2) be extend distally and the protrusion (5) is the first causes the radial deformation of the wide sections (2') of the rods (2) during the axial movement of the probe relative to the tubular nail and then causes the node (3) can to move towards the head (1), which in turn causes a radial expansion of the tubular nail in the proximal area of its rods (2).

To successfully solve the problem of fractures of the femur, it is necessary that the proximal section of said rods (2) bulges outwards, so the rods should undergo a radial expansion in this area, pressing against the side wall of the bone and thus achieving not only an antirotational or anti-torsion-tension, so also a longitudinal tension of the bone, the anchor described in U.S. 3,512,448 does not allow the middle section to expand radially to penetrate the wall, but can expand only at the lower ends.

On the other hand in the Aginsky U.S. Patent 4,227,518, longitudinal expansion is performed by rotating a disk around a central axis and not a penetration into the porous bone, the technique described in U.S. 4,227,518 does not avoid the problems

of anti-torque or anti-tension-torsion in order to keep the injured bone fixation, so it is not clear that with the combination of both patent documents can be obtained the results described in this application.

The head of the tubular nail and the design of the intramedullary nail allowing sequential fixation to the bone both defined in claim 1 (European B1) are neither disclosed in their present form in any documents found in the available prior art.

For the purpose of clarity in the description and the attached claims are made with the following clarification:

The reference sign 2 in claim 6 has been understood as indicating the rods consisting of a proximal section without reference sign in the drawings, a node 3 and the distal section 2'.

The assembly mentioned in claims 6 and 7 has been understood as consisting of the intramedullary nail 1 and the support 6.

Thus, these patents do not teach or suggest a medullary nail as set forth in claim 6 in which the nail provides thin rods in the middle and wide sections which are independent at their free ends at the distal end. Furthermore, the claim sets forth the structure which causes the nail to be driven into the spongy bone tissue surrounding the medullary and then causes thin rods to be expanded in the medial portion of the medullary. It is noted that neither of the cited references includes thin rods in the medial section of the nail and wide sections having independent free ends at the distal section of the nail and neither reference teaches or suggests the use of a protrusion which first causes radial deformation of the wide sections during axial movement of the probe and then causes radial expansion of the thin rods in the proximal section, as set forth in claim 6. Accordingly, claim 6 is properly patentable to Applicant.

Claim 7 defines the nail including the support 6 with a stepped axial hole for attachment to the head and a radial fin with a pair of holes for screwing the support to the bone. Neither of the references teaches or suggests such a support.

Claim 8 defines the nail of Fig. 7 including a threaded section for the attachment of a template for drilling into the bone for the subsequent implantation of a collar to move the threaded rod. Thus, claims 6-8 are properly patentable to Applicant.

Claim 9 defines the nail as described in paragraphs [0031] - [0033] in which it is pointed out that the free terminal ends of the rods area adapted to be driven into the spongy tissue lining the medullary cavity. As defined in claim 9, in the present invention, the section between the head (1) and the protrusion (5) is expanded radially

along the entire bone by means of a plurality of rods which extends beyond the node (3) bulging radially intermediate zone of the nail and thus achieving an anti-rotational or anti-torsion-tension and also a longitudinal tension of the bone, which helps it to knit together. At the distal end, the filaments (2') are driven into the spongy tissue and are controllable and almost reach a perpendicular position relative the bone, which gives the nail greater stability. The elastic properties of the nail generate longitudinal tension when the patient puts weight on the leg, thus helping the bone to knit together. The prior art structures do not allow an ideal pressure on the walls of the bone and it is impossible that the filaments of the prior art structures are inserted into the porous bone area due to the short length of the terminal elements, do not allow adequate pressure within bone. However, in the present application, pressure is exercised by a plurality of rods and the bulge in the middle area allows for better association with bone. The Summerlin patent is designed to anchor the fastener in a straight-walled cylindrical hole which closely surrounds the fastener. The tail end part 15 has arms 17 which bite into the cylindrical hole. This patent would not suggest a structure as claimed by Applicant in which the terminal part of the nail has wide sections (2') which are adapted to almost reach perpendicular position to be driven into spongy tissue lining a medullary cavity. Claim 9 is therefore patentable to Applicant.

Early and favorable reconsideration leading to prompt passage of the case to issue is respectfully requested.